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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/742,785

12/20/2000

William J. Curatolo

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1613

MAIL DATE

DELIVERY MODE

02/16/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/742,785	Applicant(s) CURATOLO ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,29,156 and 164-168 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,29,156 and 164-168 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner acknowledges receipt of request for power of attorney, request for extension of time, IDS, amendment and remarks, all filed 11/30/2010. Claims 1 and 164 are amended. Claim 2 is canceled. Claims 1, 29, 156 and 164-168 are pending.

Response to Arguments

2. Previous rejections such as the rejection of claims 1, 2, 29, 164, 165 and 167 and 168 U.S.C. 102(e) as being anticipated by Curatolo et al. (US 6,548,555 B1) and the rejection of claims 1, 2, 29, 156, 164, 165, 166, 167 and 168 under 35 U.S.C. 103(a) (clm. 156, 166) as being obvious over Curatolo et al. (US 6,548,555 B1) in view of Busch et al. (US 6,110,918) are withdrawn in view of applicant's declaration under 37 CFR 1.131 antedating the filing date of US 6,548,555.

3. The rejection of claims 1, 29, 164 and 166-168 under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 5,496,561) is also withdrawn in view of applicant's persuasive argument that the polymer and the drug are not in simple physical mixture where the mixture contains drug particles and polymer particles.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

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claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 29, 156 and 164-168 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-20, 29, 30 and 33-52 of U.S. Patent No. 6,548,555 in view of applicant's admitted prior art.

6. The instant claims are directed to a composition comprising particles of crystalline drug and particles of concentration enhancing polymer that is selected from cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methyl cellulose phthalate and hydroxypropyl methyl cellulose acetate succinate. The issued claims are directed to similar compositions except that the drug in the issued claims is amorphous. However, drugs are known to take amorphous and crystalline forms. This is evidenced by applicant's admitted prior art in which it is said that amorphous as well as crystalline drugs can be used in the formulation

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(see at least paragraph [0044] of the published application). Therefore, it would be obvious to one of ordinary skill in the art to use crystalline or amorphous drug in a composition in which the concentration enhancing polymer is used to enhance the solubility of a drug.

7. With regards to the drug and polymer present as particles in a physical state, gleaned from the disclosure of 6,548,555 reveals that polymer and the drug are in simple physical mixture with the drug and polymer present as particles (see at least column 5, lines 1-36).

8. Furthermore, the generic recitation of drugs broadly encompasses any drug including those recited in claims 29 and 156.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-272-0594.

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12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618